

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ANWAR EYE CENTER, INC.**

I PREAMBLE

Anwar Eye Center, Inc. ("AEC") hereby agrees to enter into this Corporate Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of certain integrity measures to ensure compliance with the requirements of the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by AEC, by AEC's employees and agents, by any entity in which AEC is an owner or has a control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) and such entity's employees and agents, and by all third parties with whom AEC may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs (the preceding shall collectively be referred to hereafter as "Covered Persons"). Contemporaneously with this Agreement, AEC is entering into a Settlement Agreement (the "Settlement Agreement") with the United States. This Agreement is incorporated by reference into the Settlement Agreement.

Prior to the execution of this Agreement, AEC voluntarily established a compliance plan known as the Practice Compliance Program ("Program"). That compliance plan provides for policies and procedures and, as represented by AEC in this Agreement, is aimed at ensuring that its participation in the Federal health care programs (which includes any requests for payments) is in conformity with the statutes, regulations and other directives applicable to the Federal health care programs. Therefore, pursuant to this Agreement, AEC hereby agrees to maintain in full operation the compliance plan as it relates to the submission of claims for services for the term of this Agreement. The compliance plan may be modified by AEC as appropriate, but at a minimum, shall comply with the corporate integrity obligations enumerated in this Agreement.

II TERM OF THE AGREEMENT

Except as otherwise provided in this Agreement, the period of compliance obligations assumed by AEC under this Agreement shall be three (3) years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory executes this Agreement.

III INTEGRITY OBLIGATIONS

Pursuant to this Agreement, and for its duration, AEC will make the following corporate integrity obligations features of its Program, which shall be maintained or established in accordance with the provisions below:

A. COMPLIANCE OFFICER

AEC has represented to OIG that, pursuant to its Program, it has created the position of Compliance Officer. At a minimum, the Compliance Officer must continuously be charged with the responsibility for the day-to-day compliance activities in furtherance of the obligations assumed herein, as well as for any reporting obligations established under this Agreement. If a new Compliance Officer is designated during the term of this Agreement, AEC shall notify OIG, in writing, within thirty (30) days of such a change.

B. CODE OF CONDUCT

AEC represents that it has established a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within ninety (90) days of the effective date of this Agreement. AEC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, continue to set forth:

1. AEC's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
2. AEC's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with AEC's own Policies and Procedures as implemented pursuant to Section III.C (including the requirements of this Agreement);

3. the requirement that all of AEC's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by AEC suspected violations of any Federal health care program requirements or of AEC's own Policies and Procedures;
4. the possible consequences to both AEC and Covered Persons of failure to comply with all Federal health care program requirements and with AEC's own Policies and Procedures or of failure to report such non-compliance; and
5. the right of all individuals to use the Confidential Disclosure Program described in Section III.F, and AEC's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the Agreement, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by AEC's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after becoming a Covered Person or within ninety (90) days of the effective date of this Agreement, whichever is later.

AEC shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within thirty (30) days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty (30) days of the finalization of such revisions.

C. WRITTEN POLICIES AND PROCEDURES

AEC shall continue to develop and implement written Policies and Procedures within ninety (90) days of the effective date of this Agreement, which written Policies and Procedures shall address the following:

1. AEC's commitment to adhere to honest and accurate billing practices;

2. The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards;
3. The assignment of appropriate CPT codes, including, but not limited to, the proper use of CPT codes when billing for new patients;
4. The requirement that all AEC employees and contractors shall be appropriately and validly licensed;
5. A mechanism for employees and agents to make inquiries and reports regarding compliance with medical practice standards and Federal health care program reimbursement standards without risk of retaliation or other adverse effect; and
6. AEC's commitment not to hire or engage as a contractor any Ineligible Person. For the purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility. To prevent hiring or contracting with any Ineligible Person, AEC shall screen all prospective employees and prospective contractors prior to engaging their services by: (i) requiring applicants to disclose whether they are Ineligible Persons; and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epfs.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) these lists will hereinafter be referred to as the "Exclusion Lists").

Within ninety (90) days of the effective date of this Agreement, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually, AEC shall assess and update as necessary the Policies and Procedures. Within thirty (30) days of the effective date of any revisions, the

relevant portions of any such revised Policies and Procedures shall distributed to all individuals whose job functions are related to those Policies and Procedures.

D. TRAINING AND CERTIFICATION

1. General Training. Within thirty (30) days of the effective date of this Agreement, AEC shall provide at least one hour of general training to each Covered Person. This training shall explain AEC's:

- a. Obligations under this Agreement; and
- b. Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within thirty (30) days of becoming a Covered Person or within ninety (90) days after the effective date of this Agreement, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. Specific Training. Within thirty (30) days of the effective date of this Agreement, each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall be trained in the proper reimbursement standards, program policies, and verification and compliance procedures to ensure the propriety and accuracy of claims for services and items furnished to Federal health care program patients. The training shall be designed to ensure that all of AEC's Relevant Covered Persons are aware of all applicable Federal health care program statutes, regulations and guidelines and the consequences (e.g., overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the Federal health care programs, etc.) both to the individual and AEC that may ensue from any violation of such requirements.

At a minimum, the training sessions shall cover the following topics:

- a. All applicable Federal health care program statutes, rules, regulations, and guidelines related to reimbursement, and the legal sanctions for improper billing or other violations of these standards;

b. The written Policies and Procedures developed pursuant to Section III.C, above; and

c. Examples of proper and improper billing practices.

AEC shall arrange for each new Relevant Covered Person to participate in such training no later than thirty (30) days after the person begins to work for AEC. Until the person has received the requisite training, such new Relevant Covered Person shall work under the direct supervision of an AEC employee who has received the required training.

This training program shall provide for no less than three (3) hours of training annually for each Relevant Covered Person.

AEC shall require each employee and agent to sign and date a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the Policies and Procedures and all applicable Federal health care program standards addressed in training. These certifications will be maintained by AEC and shall be made available for inspection by OIG or its duly authorized representative(s). At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

E. INDEPENDENT CLAIMS REVIEWS

On at least an annual basis and for the duration of this Agreement, AEC agrees to contract with an independent third-party reviewer (e.g., a health care billing auditor or a consultant) (hereinafter the "Independent Reviewer") to undertake a Claims Review of a statistically valid sample of the claims submitted by AEC and its agents and/or employees to the Federal health care programs. The Claims Review is described in Appendix A, which is incorporated by reference herein. The purpose of the Claims Review is to determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of Federal health care program statutes, regulations, requirements, and reimbursement policies and procedures. These reviews shall cover the preceding one (1) year period and shall seek to determine that the claims submitted to the Federal health care programs are for medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded

and billed. At the conclusion of each review, the Independent Reviewer shall prepare a Claims Review Report, as described in Appendix A. A copy of this report shall be included in AEC's Annual Reports to OIG.

In the event that OIG has reason to believe that: (a) AEC's Claims Review fails to conform to the requirements of this Agreement or (b) the findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complies with the requirements of this Agreement and/or the accuracy of the Claims Review. AEC agrees to pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated before one year after the final submission is received by OIG.

F. NOTIFICATION OF GOVERNMENT INVESTIGATION OR LEGAL PROCEEDINGS

Within thirty (30) days of discovery, AEC shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that AEC has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. AEC shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV REPORTING

A. OVERPAYMENTS

1. **DEFINITION OF OVERPAYMENT.** For the purposes of this Agreement, an "overpayment" shall mean the amount of money AEC has received in excess of the amount due and payable under any Federal health care program requirements. AEC may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."
2. **REPORTING OF OVERPAYMENTS.** If, at any time, AEC identifies or learns of any overpayments, AEC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within thirty (30) days of discovery and take remedial

steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement.

B. MATERIAL DEFICIENCIES

1. Definition of Material Deficiency. For the purposes of this Agreement, a "Material Deficiency" means anything that involves:
 - (a) a substantial overpayment;
 - (b) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or
 - (c) a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

2. Reporting of Material Deficiencies. If AEC determines that there is a Material Deficiency, AEC shall notify OIG, in writing, within thirty (30) days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:
 - (a) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the

notification to the payor required in section IV.A.1, and shall include all of the information on the Overpayment Refund Form, as well as:

- (i) the payor's name, address, and contact person to whom the overpayment was sent; and
- (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;
- (b) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (c) a description of AEC's actions taken to correct the Material Deficiency; and
- (d) any further steps AEC plans to take to address the Material Deficiency and prevent it from recurring.

V OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of AEC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of AEC's locations for the purpose of verifying and evaluating: (a) AEC's compliance with the terms of this Agreement; and (b) AEC's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by AEC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for the purposes of this provision, OIG or its duly authorized representative(s) may interview any of AEC's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. AEC agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AEC's employees may elect to be interviewed with or without a representative of AEC present.

VI REPORTS

A. IMPLEMENTATION REPORT

Within one hundred and twenty (120) days of the effective date of this Agreement, AEC shall provide OIG with a written report summarizing the status of its implementation of its requirements under this Agreement. This report, known as the "Implementation Report," shall include:

1. The name, address, phone number and position description of the Compliance Officer required by Section III.A;
2. A copy of AEC's Code of Conduct as described in Section III.B;
3. A certification by AEC's Compliance Officer attesting that all employees have completed the initial training required by Section III.D as well as a summary of what the training included. The training materials will be made available to OIG upon request;
4. A copy of the written Policies and Procedures required by Section III.C of this Agreement;
5. A list of all of AEC's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number; and
6. A certification stating that AEC's Compliance Officer has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon his or her inquiry, the information is accurate and truthful.

B. ANNUAL REPORTS

AEC agrees to make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures AEC has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented pursuant to Section III.D of this Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in Section III.D of this Agreement;
2. Any change in the identity or position, or any material change in the duties, of the Compliance Officer as set forth in Section III.A;
3. Copies of any revisions or amendments made to the Policies and Procedures pursuant to Section III.C;
4. A copy of the audits and reviews conducted pursuant to Section III.E of this Agreement relating to the year covered by the Annual Report; and a complete description of the findings made during the reviews;
5. A certification by the Compliance Officer that:
 - a. All Covered Persons have completed any Code of Conduct certifications required by Section III.B;
 - b. All Covered Persons have completed the applicable training and executed the certification(s) required by Section III.D; and
 - c. AEC has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs;

The documentation supporting this certification shall be made available to OIG, upon request;

6. A summary of Material Deficiencies (as defined in Section IV.B) identified during the reporting period and the status of any corrective and preventative action relating to all such Material Deficiencies;
7. A report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
8. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.F. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
9. A description of all changes to the most recently provided list (as updated) of AEC's locations (including locations and mailing addresses) as required by Section VI.A.6, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program identification number(s), and the contractor name and address that issued each provider identification number; and
10. A certification signed by AEC's Compliance Officer certifying that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon his or her inquiry, the information is accurate and truthful.

The Annual Reports shall be due within ninety (90) days of the end of the one-year period covered by the Annual Report. The first one-year period shall commence on the effective date of this Agreement.

C. DESIGNATION OF INFORMATION

AEC shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. AEC shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VII NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with Section XI below, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

OIG: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Telephone: 202-619-2078
Facsimile: 202-205-0604

AEC: Dr. Mohammad F. Anwar
Anwar Cataract Center
1500 Lafayette Avenue
Moundsville, WV 26041
Telephone: 304-845-0908
Facsimile: 304-845-1250

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For the purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VIII BREACH AND DEFAULT PROVISIONS

AEC is expected to fully and timely comply with all of its obligations under this Agreement.

A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS.

As a contractual remedy, AEC and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AEC fails to have in place any of the following:
 - a. a Compliance Officer as described by Section III.A.;
 - b. a Compliance Committee as described by Section III.A;
 - c. a written Code of Conduct as described by Section III.B;
 - d. written Policies and Procedures as described by Section III.C; and
 - e. a requirement that Covered Persons be trained as described in Section III.D.
2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AEC fails to retain an Independent Reviewer, as required in Section III.E.
3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AEC fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.
4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day AEC employs or contracts with an Ineligible Person (as defined in Section III.C.6) and that person: (i) has responsibility for, or involvement with, AEC's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty

described in this paragraph shall not be demanded for any time period during which AEC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.C.6) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day AEC fails to grant access to the information or documentation as required in Section V of this Agreement. (This Stipulated Penalty shall begin to accrue on the date AEC fails to grant access.)
6. A Stipulated Penalty of \$1,000 for each day AEC fails to comply fully and adequately with any obligation of this Agreement not already covered in Sections VIII.A 1-5. In its notice to AEC, OIG shall state the specific grounds for its determination that AEC has failed to comply fully and adequately with the obligation(s) at issue and steps AEC must take to comply with this Agreement. (This Stipulated Penalty shall begin to accrue ten (10) days after the date that OIG provides notice to AEC of the failure to comply.)

B. TIMELY WRITTEN REQUESTS FOR EXTENSIONS.

AEC may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after AEC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after AEC receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. PAYMENT OF STIPULATED PENALTIES.

- 1 **DEMAND LETTER.** Upon a finding that AEC has failed to comply with any of the obligations described in section VIII.A and after determining that Stipulated Penalties are appropriate, OIG shall

notify AEC of: (a) AEC's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. **RESPONSE TO DEMAND LETTER.** Within ten (10) days of the receipt of the Demand Letter, AEC shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section VIII.E. In the event AEC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AEC cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under section VIII.D.
3. **FORM OF PAYMENT.** Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VII.
4. **INDEPENDENCE FROM MATERIAL BREACH DETERMINATION.** Except as set forth in Section VIII.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that AEC has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section VIII.D, below.

D. EXCLUSION FOR MATERIAL BREACH OF THIS AGREEMENT.

1. **DEFINITION OF MATERIAL BREACH.** A "material breach" of this CIA means:
 - a. a failure by AEC to report a material deficiency, take corrective action and make the appropriate refunds, as required in Section IV;
 - b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section VIII.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section VIII.C; or

d. a failure to retain and use an Independent Reviewer in accordance with Section III.E.

2. **NOTICE OF MATERIAL BREACH AND INTENT TO EXCLUDE.** The Parties agree that a material breach of this Agreement by AEC constitutes an independent basis for AEC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that AEC has materially breached this Agreement and that exclusion should be imposed, OIG shall notify AEC of: (a) AEC's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. **OPPORTUNITY TO CURE.** AEC shall have thirty (30) days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. AEC is in full compliance with this Agreement;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) AEC has begun to take action to cure the material breach; (ii) AEC is pursuing such action with due diligence; and (iii) AEC has provided to OIG a reasonable timetable for curing the material breach.

4. **EXCLUSION LETTER.** If at the conclusion of the 30-day period, AEC fails to satisfy the requirements of Section VIII.D.3, OIG may exclude AEC from participation in the Federal health care programs. OIG will notify AEC in writing of its determination to exclude AEC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section VIII.E, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is

not automatic. If at the end of the period of exclusion, AEC wishes to apply for reinstatement, AEC must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. DISPUTE RESOLUTION.

1. **REVIEW RIGHTS.** Upon OIG's delivery to AEC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, AEC shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within ten (10) days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty-five (25) days of receipt of the Exclusion Letter.
2. **STIPULATED PENALTIES REVIEW.** Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether AEC was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. AEC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders AEC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless AEC requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable twenty (20) days after the DAB issues its decision.

3. **EXCLUSION REVIEW.** Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:
- a. whether AEC was in material breach of this Agreement;
 - b. whether such breach was continuing on the date of the Exclusion Letter; and
 - c. whether the alleged material breach could not have been cured within the thirty (30) day period, but that:
 - (i) AEC had begun to take action to cure the material breach within that period;
 - (ii) AEC has pursued and is pursuing such action with due diligence; and
 - (iii) AEC provided to OIG within that period a reasonable timetable for curing the material breach and AEC has followed the timetable.

For the purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for AEC, only after a DAB decision in favor of OIG. AEC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude AEC upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that AEC may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect twenty (20) days after the DAB decision.

4. **FINALITY OF DECISION.** The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the Parties to this Agreement agree that the DAB's decision (or the ALJ's decision if

not appealed) shall be considered final for all purposes under this Agreement.

IX DOCUMENT AND RECORD RETENTION

AEC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six (6) years (or longer if otherwise required by law).

X DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify AEC prior to any release by OIG of information submitted by AEC pursuant to its obligations under this Agreement and identified upon submission by AEC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, AEC shall have the rights set forth at 45 C.F.R. § 5.65(d). AEC shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

XI EFFECTIVE AND BINDING AGREEMENT

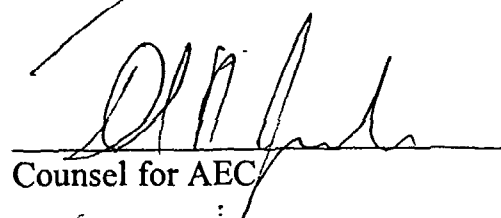
Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is reached, and into which this Agreement is incorporated, AEC and OIG agree as follows:

1. This Agreement shall become final and binding only upon signing by each respective party hereto;
2. This Agreement shall be binding on the successors, assigns, and transferees of AEC;
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement; and
4. The undersigned AEC signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

ON BEHALF OF ANWAR EYE CENTER, INC.


Dr. Mohammad F. Anwar
President, AEC

July 24, 2000
Date


Counsel for AEC

July 24, 2000
Date

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

Date

ON BEHALF OF ANWAR EYE CENTER, INC.


Dr. Mohammad F. Anwar
President, AEC

Date

Counsel for AEC

Date

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris, Esquire
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U. S. Department of Health and Human Services



Date